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**Comments by the Government of Japan on the United States' Interim Final Rule "Prior Notice of Imported Food" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**  
**(DOCKET No. 2002N-0278)**

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The Government of Japan appreciates the opportunity to provide comments as follows on the United States' Interim Final Rule of "Prior Notice of Imported Food" (hereinafter referred to as "the Rule") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the United States' Federal Register dated October 10, 2003 and notified to the WTO Members dated April 16, 2004 (G/SPS/N/USA/690/Add.6).

1. There are cases where the procedures for prior notice are carried out by agents in the U.S. who act on behalf of Japanese companies. However, in some cases, it is difficult to provide such agents with necessary information for prior notice, sufficiently ahead of the arrival of the freight. Since time difference between Japan and the U.S. makes it difficult for the agent to start submitting prior notice immediately upon the reception of necessary information, some goods transported by air, as well as by sea, have actually missed the appointed period of prior notice. To resolve this problem, the Government of Japan requests that the information related to the prior notice be well managed in accordance with flight or ship code numbers, and that prior notice be accepted until immediately before the arrival of goods.
2. The prior notice of imported food needs to be filed by specialists on behalf of exporters because the procedure is more complicated than that of the registration of food facilities. There seem to be many unnecessary items of information such as addresses of registered facilities required to provide in the notice in view of the original purpose of the Rule, that is, prevention of bioterrorism. In order not to excessively burden the exporters, the procedure of notice should be simplified, and its contents should be limited to the minimum such as a shipper's name and its contact point, a registration number of food facility and product codes.
3. Before the interim final rule becomes final, meetings for explanation should be held anew in

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order to obtain understanding of all the parties concerned on the Rule. The system should also be developed to be as efficient as possible through hearings from a variety of stakeholders.

4. Mail users are requested to submit a prior notice to FDA through FDA's PN System Interface (PNSI). This means that only those who can access to the Internet and can well understand English may be able to send foods to the U.S. by mail. The other mail users will have to bear unreasonable disadvantages and unequal treatment.

Additionally, mail items containing foods without a PN Confirmation Number will be detained at the port of entry in the U.S. for 72 hours, and thereafter, destroyed or returned to the sender. Although most foods are not categorized as prohibited items of which the United States Postal Service (USPS) informed the Universal Postal Union (UPU), they will be unable to be delivered to the addressee if they do not have PN Confirmation Numbers. It is clear that the rights of senders to mail and of addressees to receive will be extremely undermined by such treatments.

The Government of Japan therefore strongly requests the U.S. Government to take the following measures:

(1) to simplify the prior notice requirements and procedures for mail users concerning PNSI;

Example: "Entry Type" is currently being classified into "Mail" and "Mail (Non-commercial Sender)." The latter should be allowed to omit filling-in of certain information such as the "Product Code."

(2) to establish PNSI by languages other than English including Japanese;

(3) to put in place necessary arrangements for delivering food-containing mail items to the addressee after inspected and considered non-problematic by FDA or Customs even if a prior notice does not accompany the items;

(4) to make necessary arrangements to facilitate the use of fax and mail, other than the Internet for the prior notice;

(5) to inform all the Member States of the UPU of all the requirements regarding postal service established by FDA for the prevention of bioterrorism; and

(6) to establish an inquiry service at relevant U.S. Government agencies including all the U.S. Embassies abroad.

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**Comments by the Government of Japan on the United States' Interim Final Rule  
"Registration of Food Facilities" Under the Public Health Security and Bioterrorism  
Preparedness and Response Act of 2002 (DOCKET No. 2002N-0276)**

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The Government of Japan appreciates the opportunity to provide comments as follows on the United States' Interim Final Rule of "Registration of Food Facilities" (hereinafter referred to as "the Rule") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the United States' Federal Register dated October 10, 2003 and notified to the WTO Members dated April 16, 2004 (G/SPS/N/USA/691/Add.6) and April 19, 2004 (G/TBT/N/USA/32/Add.4).

1. The Rule provides that only one U.S. agent must be assigned to each foreign facility for its registration. Japanese small or medium-sized companies in Japan thus will be limited to do business only through a single agent and will most likely face difficulties in maintaining or expanding their market by approaching various agents. In this regard, the companies should be allowed to register more than one U.S. agents for each facility so that their export business to the U.S. will not be unreasonably undermined.

2. Due to the burden incurred by the registration process, some Japanese companies have actually been discouraged to export to the U.S. and consequently withdrawn from food export business to the U.S. While it is difficult, however, to estimate the specific magnitude of such negative effects, the Government of Japan believes that the huge workload related to customs clearance procedures has decreased the number of export enterprises as well as export opportunities. The Government of Japan thus requests the U.S. Government to ease these burdens as much as possible.